

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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THE PROCTER & GAMBLE COMPANY,	:	
	:	Civil Action No. 07-8379 (RJS)
Plaintiff,	:	
	:	
v.	:	DECLARATION OF
ULTREO, INC.,	:	<u>JACK GALLAGHER</u>
	:	
Defendant.	:	
-----X		

I, JACK GALLAGHER, hereby declare under penalty of perjury as follows:

Background

1. I am Chief Executive Officer and President of Ultreo, Inc. ("Ultreo"), a corporation organized under the laws of the State of Washington and located in Redmond, Washington. I submit this declaration, which is based on my personal knowledge, except as otherwise indicated, in opposition to The Procter & Gamble Company's ("P&G") motion for preliminary injunctive relief.

2. Prior to founding Ultreo in 2003, I was President of Optiva Corporation ("Optiva"), which developed the Sonicare® power toothbrush in the early 1990s. Under my stewardship, annual sales of the Sonicare® grew from \$130 million to \$300 million. Eventually, Optiva was acquired by Philips Electronics, and now the Sonicare® brand has the largest share in dollars in the market for premium power toothbrushes.

3. Prior to joining Optiva, I spent over 20 years with Johnson & Johnson in various sales, marketing and management positions. I have extensive experience in the fields of consumer products, marketing and the oral health industry.

4. I hold a Bachelor of Science degree and a Master's in Business Administration. I received both of these degrees from Seton Hall University.

The Development Of The Ultreo® Toothbrush

5. I formed Ultreo with former scientists, engineers and executives of Optiva to develop a power toothbrush utilizing ultrasound technology. This product development project was undertaken in conjunction with Pierre D. Mourad, Ph.D., an Associate Professor in the Departments of Neurological Surgery and Pediatric Dentistry at the University of Washington ("UW"), and a Principal Physicist at the Center for Industrial and Medical Ultrasound in the Applied Physics Laboratory at UW (the "UW Ultrasound Center").

6. As set forth in the Declaration of Dr. Lawrence A. Crum, the UW Ultrasound Center is the leading academic research facility relating to ultrasound technology in the United States. The UW Ultrasound Center is involved in research concerning the use of ultrasound waves for medical purposes such as ablating tumors and gallstones in human patients. The UW Ultrasound Center has also conducted extensive research concerning the cleaning capabilities of ultrasound, whether it is used to clean jewelry, semi-conductors or surgical instruments. For many years in the dental profession, ultrasound has been used in dental scalers to conduct high pressure professional dental cleanings.

7. Dr. Mourad was intimately familiar with the cleaning capabilities of ultrasound-activated microscopic bubbles from his work at the UW Ultrasound Center. Dr. Mourad believed that combining ultrasound technology with a sonic power toothbrush would generate ultrasound-activated bubbles that could augment the cleaning capabilities of the sonic-powered bristle activity.

8. There had been prior examples of power toothbrushes that employed ultrasound technology in the market. However, those products were not successful because, among other things, they did not embody a means whereby the ultrasound waves could be directed toward the

bristle tips without dissipating into the air, or without being interfered with by the bristles.

9. Dr. Mourad devised a method of using an ultrasound waveguide, placed in the center of the brushhead, which would channel the ultrasound energy toward the tips of the bristles and into the microbubbles created by these bristles. Placing the waveguide right in the center of the front of the brushhead ensured that the bristles would not interfere with the ultrasound waves. The ultrasound would activate the microbubbles by causing them to pulsate — i.e., expand and contract rapidly — which would generate scrubbing and cleaning forces in the mouth.

10. The development of the Ultreo® toothbrush was the culmination of a prolonged and expensive development process. Dr. Mourad and his staff at UW, working closely with engineers and scientists at Ultreo, including Dr. James Christopher McInnes, researched, developed and tested numerous prototypes over a 3½ year period. Ultreo spent in excess of \$5.5 million in research and development costs in connection with this process.

11. The novelty of Dr. Mourad's invention is evidenced by the fact that Ultreo has been issued a utility patent covering aspects of the ultrasound components of its toothbrush by the U.S. Patent and Trademark Office. Moreover, the University of Washington has been issued a U.S. patent on its original invention. Copies of the Ultreo® and UW patents are attached hereto as Exhibit A.

12. Ultreo has conducted extensive clinical research into the safety and efficacy of its product. Indeed, Ultreo was awarded three research grants from the Washington Technology Center, and two additional grants from the prestigious National Institutes of Health. These grants totaled nearly \$2 million and were issued only after the granting bodies had conducted a thorough review and approval of Ultreo's® procedures and testing protocols.

13. As set forth in the Declaration of Dr. McInnes, Ultreo's clinical research shows that Ultreo® removes up to 95 percent of hard-to-reach plaque in the first minute of brushing, reduces gingivitis and removes stains for whiter teeth. As Dr. McInnes and Dr. Joel Berg, an expert in the field of dental research, further explain, Ultreo has also conducted laboratory studies with respect to the safety and efficacy of its product. Ultreo publishes this research on its website and in pamphlets that are distributed to dental professionals so that these sophisticated and knowledgeable individuals can review that research and form their own opinions as to the merits of the Ultreo® power toothbrush.

Ultreo's Marketing And Sales Efforts

14. By February 2007, Ultreo finally had a product that could be brought to market. Ultreo began to market its brush to dental professionals, such as dentists, dental hygienists and dental assistants. Ultreo advertised the product in dental journals, displayed the product at dental trade shows, and conducted direct marketing presentations in dental offices. Ultreo's plan was to focus first on the professional market and to ascertain whether this demanding and highly sophisticated population would be receptive to the Ultreo®.

15. To date, Ultreo has achieved approximately \$4 million in sales. Approximately 60 percent of these sales have been to dental professionals. These professionals have purchased the product for themselves and for resale to their patients. Sales to dental professionals provide Ultreo with vital feedback concerning its product. Dental professionals who have recommended and sold Ultreo® toothbrushes to their patients are then able to observe the effects of use of the brush on their patients' dental health and advise Ultreo regarding the product's performance.

16. The Ultreo® has been remarkably well-received by the dental community. The company has received numerous testimonials from dental professionals stating that they and their

patients very much like using the product and that they have noticed an improvement in the dental health of their patients who are using the brush. The Ultreo® has received favorable reviews in dental publications such as *Inside Dentistry* and *Dental Town Magazine*.

17. Ultreo's toothbrush is now being marketed directly to consumers. The Ultreo® has been featured in *Esquire Magazine* as one of the "best products for grooming," and has been named by *Popular Science* as a "must-have" product. It has received favorable mention in *New York Magazine*, *Mr. Gadget*, *Domestic Diva* and on *www.momfinds.com*.

18. The Ultreo® is available for purchase directly by consumers over the Internet, at e-tail sites such as *amazon.com* or *drugstore.com*. It is also on display at certain specialty stores that feature cutting-edge products such as The Sharper Image and Hammacher Schlemmer, and in catalogs such as *Frontgate*.

19. Consumer reactions based on the use of the Ultreo® have been extremely positive. Ultreo commissioned the consumer research firm Coopers Roberts Research to conduct a survey to assess consumer reaction to its product (the "Consumer Use Study"). Approximately two hundred and seventy consumers were recruited to try the Ultreo® toothbrush at home for a one-month period. Among the 268 who completed the study, 95 of them were Oral-B® rechargeable users and 105 of them were Sonicare® rechargeable users.

20. The response, polled at the conclusion of the one-month period of usage, was overwhelmingly favorable to the Ultreo® toothbrush. Approximately 70 percent of users who expressed a preference between the Ultreo® and their existing power toothbrush said they preferred the Ultreo®. Approximately 60 percent of both the Oral-B® and the Sonicare® users who expressed a preference said they preferred the Ultreo® toothbrush. Eight out of ten of all users said that as a result of using the Ultreo®, they would be switching to that product. This is

obviously what P&G is most concerned about.

21. Moreover, 60 percent or more of all users indicated that they liked the Ultreo® because it made their teeth feel "cleaner" or "smoother." It cannot be over-emphasized that these results were obtained on the basis of actual product usage. Accordingly, P&G's Wayne Randall's reliance upon the results of this study as support for his claim regarding the effects of Ultreo's® advertising is totally misplaced. A copy of the June 2007 Consumer Use Survey ("Toothbrush IHUT") is annexed hereto as Exhibit B.

Ultreo Will Be Seriously Harmed By The Issuance Of A Preliminary Injunction

22. This month, Ultreo launched its product with certain premium retail stores such as Macy's, Bloomingdale's, Linens & Things and Bartell Drugs. It is critically important to Ultreo's future prospects that this launch occur smoothly and successfully. Ultreo cannot afford to have this consumer launch derailed by P&G through this litigation.

23. P&G's Oral-B® brand power toothbrush controls close to 50 percent of the market (in dollars) in the premium power toothbrush category. In the past, Oral-B has acted aggressively to protect its market dominance and to prevent new market entrants from competing with it. Oral-B pursued this very strategy against Optiva early in the life of that company, repeatedly suing Optiva for false advertising.

24. I believe that P&G has initiated this lawsuit in a deliberate attempt to interfere with Ultreo's entry into the market. Indeed, confidential P&G documents obtained during the course of discovery in this action show P&G's true motives. An internal P&G e-mail dated February 13, 2007, for example, sounded the initial alarm at P&G, as follows:

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A copy of this e-mail is annexed hereto as Exhibit C (PG006813-16 at PG006814).

25. P&G first complained about Ultreo's advertising in March of this year. In an effort to avoid litigation, we reluctantly agreed to modify our advertising claims as P&G requested. However, P&G's attorneys responded by demanding even more changes to our ads, many of which were inconsistent with requests they had made earlier.

26. The last time P&G's attorney corresponded with us was in late June 2007. Then, three months later, in late September 2007 — a full six months from when P&G first complained about Ultreo's advertising — P&G commenced this action. The fact that P&G waited six months to sue Ultreo demonstrates that it is not being irreparably injured by our advertising.

27. Furthermore, it is certainly not coincidental that P&G filed this lawsuit and issued a press release disclosing the litigation to the public on the opening day of the American Dental Association ("ADA") annual convention on dental products being held in San Francisco, California. That was a deliberate effort by P&G to adversely affect our efforts to market our product to dental professionals at this all-important industry convention. It was also a ruthless public attempt to embarrass and disparage our product, company, and employees. *See* P&G September 27, 2007 Press Release at Exhibit D hereto.

28. As a fledging company, Ultreo is in a precarious financial position right now.

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29.

30. A temporary injunction will also irreparably harm Ultreo's goodwill among dental professionals that it has just begun to develop. This goodwill is critical to Ultreo's success as a company. Ultreo's expectation is that dental professionals who like the Ultreo® toothbrush will recommend it to their patients. In this way, Ultreo hopes to use its goodwill among dental professionals to obtain goodwill among consumers. Ultreo's sales show that this effort is beginning to bear fruit. However, Ultreo's goodwill will be irreparably harmed if P&G is granted a preliminary injunction, because such an event will likely cause dental professionals to question the efficacy of the Ultreo® toothbrush.

31. Ultreo manufactures its product in Redmond, Washington, where its main offices are located. We employ 140 people who are responsible for manufacturing, production, packaging and shipping, marketing, sales, and accounting, as well as scientists and engineers. We make and sell a single product – the Ultreo® toothbrush.

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32. P&G's position is markedly different. P&G is a diversified product manufacturer which can survive decreased productivity and sales in one product by shifting resources to more profitable products. Indeed, P&G's 2007 Annual Report boasts that its sales total \$76 billion, that it has "more than doubled the number of brands that generate \$1 billion or more in sales each year, and now ha[s] 23 of these leading billion-dollar brands in its portfolio," and that today, P&G "is among the ten most valuable companies in the U.S." See excerpt at Exhibit E hereto.

33. P&G's Wayne Randall refers to a statement I made regarding Ultreo's goal of acquiring a 10 percent share of the power toothbrush market. That, however, is a five-year target. P&G is seeking to enjoin us now, during the pendency of this lawsuit. It is extremely unlikely that Ultreo will be able to make serious inroads into the premium power toothbrush market in a matter of months.

Ultreo's Advertising Claims

34. P&G's moving papers devote much attention to Ultreo's advertising, but neglect to mention one significant point. Ultreo does not engage in extensive advertising. It is planning to run a limited, spot television "infomercial" for a period of one week's duration. However, it has not advertised on national or local television, or placed any ads in any national circulation magazines or newspapers. Indeed, Ultreo does not even retain an advertising agency to advertise its product.

35. Ultreo has placed a few ads in specialized professional dental magazines and a few relatively small-circulation consumer magazines such as *New Beauty*. It advertises on its own website and on the websites of e-tailers such as *drugstore.com* or *amazon.com*. The

Ultreo® is also advertised in the catalogs of *Frontgate* and is available for purchase in specialty stores such as The Sharper Image.

36. Moreover, P&G's papers make reference to several claims that Ultreo no longer makes. Ultreo regularly reviews its advertising claims and makes changes based on its ongoing assessments as to what is of interest to consumers and professionals about our product. Ultreo also modified some of its claims in an effort — albeit unsuccessfully — to satisfy P&G's demands and to avoid this lawsuit. Clearly, P&G cannot claim it will be irreparably injured from advertising claims that are no longer being made. Annexed hereto as Exhibit F is a chart indicating, with respect to representative claims cited in P&G's papers, whether such claims are currently being made or not, and also reflecting whether such current claims are being made to consumers or to professionals.

37. P&G's papers conflate advertising claims that Ultreo makes to dental professionals with those it makes to consumers. These are completely different markets, with different audiences. Claims that would be important to consumers may not be relevant to professionals and vice versa. Moreover, dental professionals are extremely knowledgeable about dental claims and types of research and are able to independently assess claims and their substantiation, whether they be clinical or laboratory studies.

38. Ultreo's advertising to retail consumers does not claim that the ultrasound removes plaque bacteria. Indeed, the only instance in which such a claim was made to consumers appeared in the form of an advertisement that a catalog retailer, *Frontgate*, inadvertently published in its catalog. Annexed hereto as Exhibit G is a copy of the Ultreo® advertisement that appeared in the following month's issue of that catalog; there is no reference in that advertisement to ultrasound's ability to remove plaque bacteria. Nor does that claim

appear in the packaging that is being used in any retail market or on our website that is devoted to consumers.

39. In any event, even if such claims were implied, they would be true as shown in Ultreo's laboratory studies. Indeed, to ensure there is not even a potential for confusion, Ultreo will, in mid-December 2007, begin including an express clarification on its consumer packaging and its other advertising materials that states that "ultrasound efficacy is based on laboratory studies."

40. The claims that do appear in our retail advertising are, for example, as follows: "Microbubbles are activated by the ultrasound and transformed into pulsating bubbles," or "Ultreo is the first power toothbrush to combine ultrasound waveguide technology with precisely tuned sonic bristle action. Ultreo's bristles create microbubbles that are powerfully activated by a patented ultrasound waveguide. The result is an incredible, long-lasting feeling of clean." An example of such consumer advertising is annexed hereto as Exhibit H.

41. A "feeling of clean" is a subjective perception that we believe consumers will experience upon using our product. The human tongue is an extremely sensitive body part. It can detect even slight differences in the smoothness of gums and teeth following brushing. We have a reasonable basis for our belief that consumers will experience a "feeling of clean" when using our product because that is precisely what consumers told us about our product after using it for a month in the Consumer Use Study. As noted above, 60 percent or more of all users indicated that they liked the Ultreo® because it made their teeth feel "cleaner" or "smoother."

42. These advertising claims are hardly unique to Ultreo. Indeed, it is quite common for oral health care companies – including P&G – to use advertising that claims that their products provide consumers with a "feeling of clean" or similar sensation. Examples of such

advertisements are attached hereto as Exhibit I. By way of illustration, I note that:

- P&G's web advertisement for its Scope® Original Mint Mouthwash product claims that the product "leaves your breath feeling clean, fresh and ready to get close";
- P&G's web advertisement for its Scope® Cool Peppermint Mouthwash claims that "[t]his icy splash of peppermint has the power to reinvigorate your breath, leave your mouth feeling cool and clean – giving you the confidence to get close"; and
- P&G's web advertising for certain of its Crest® toothpaste products (Crest® Maximum Strength Sensitivity Protection Extra Whitening and Crest® Maximum Strength Sensitivity Original Formula Soothing Whitening Paste) claim that these products "leave[] teeth feeling clean."

43. There are only two claims regarding plaque removal that appear in Ultreo's consumer advertising. First, is the statement that "[s]onic action bristles with power tip creates bubbles and cleans away plaque on contact." This describes plaque being removed by the mechanical action of the bristles. This claim is indisputably true, as shown in Ultreo's clinical research, and P&G does not challenge it. Second, Ultreo's consumer ads claim that "Ultreo has been clinically proven to remove up to 95 percent of plaque from hard-to-reach areas in the first minute of brushing." This claim is also undeniably true. This was the express finding of a clinical study as described in Dr. McInnes' Declaration. Nowhere in its papers does P&G challenge the validity of that clinical study.

44. In contrast, Ultreo claims in its advertising to *dental professionals* that "Ultreo's combination of ultrasound waveguide technology and sonic bristle action can remove hard-to-reach plaque bacteria," and also that "[m]icrobubbles are activated by ultrasound and transformed into pulsating bubbles that can remove plaque bacteria." These claims are made in printed advertisements placed in dental journals and on our dental professional website. An

example of Ultreo's professional advertising is annexed hereto as Exhibit J.

45. In all instances where Ultreo makes these claims in the professional context, it plainly discloses that the claim is supported by a laboratory study. An abstract of that study is attached to Dr. McInnes' Declaration. The abstract is also available on Ultreo's website and is reprinted in brochures that are sent to dental professionals. Thus, the members of this very sophisticated audience can review and determine for themselves whether they agree with Ultreo's conclusion that the laboratory study is reliable and establishes the claim for which it is cited.

46. Nowhere in its papers does P&G provide any indication that dental professionals are being misled by our advertising claims or mistakenly believe that our supporting study is a clinical study, as opposed to a laboratory claim. Indeed, P&G admits in its brief that Ultreo plainly discloses that the ultrasound plaque removal claims are supported by "laboratory studies conducted at a leading research university." Yet, P&G argues that the laboratory studies are *in vitro* studies. Any competent dental professional knows that laboratory studies are *in vitro*, as opposed to *in vivo*, research. There is simply no deception about which P&G can complain.

P&G's Arguments Regarding Claim Substantiation

47. P&G contends that all advertising efficacy claims in the oral health industry must be supported by a clinical study. As Drs. McInnes and Berg explain in their Declarations, this contention is demonstrably false. There is no such industry rule. Indeed, Philips, which has the largest dollar market share in the premium power toothbrush category, claims in advertising aimed at dental professionals and now, to *consumers*, that its Sonicare® brush cleans teeth beyond the reach of its bristles. Indeed, "BEYOND-THE-BRISTLES" was registered as a trademark for Optiva, the creator of the Sonicare® toothbrush, in 1997 (U.S. Reg. No. 2,057,694). Examples of this Philips Sonicare® claim are annexed as Exhibit K. Significantly,

in making this claim, Philips relies *exclusively* upon laboratory studies. Thus, the power toothbrush market plainly accepts the validity of *in vitro* research.

48. Notably, P&G itself relies upon laboratory studies to support claims it makes regarding oral health products. With respect to its Crest® brand "ProHealth Rinse," P&G claims that the rinse kills "99 percent of common germs that can cause plaque, gingivitis and bad breath" – *based on laboratory studies*. Similarly, with respect to its Vicks® brand "Early Defense Foaming" hand sanitizer, P&G claims that it "fight[s] germs for up to three hours" based on laboratory testing. And, P&G also claims that its Crest® Extra White Plus Scope Toothpaste possesses "extra whitening power" as demonstrated by lab tests. Copies of these website advertisements are annexed hereto as Exhibit L. Thus, when it suits its own purpose, P&G relies upon laboratory studies — not clinical studies — to support its advertising claims.

49. As explained in the Declaration of Dr. Berg, many knowledgeable individuals in the dental research industry are suspicious of corporate-sponsored clinical research because they believe that big corporations can manipulate the test procedures or the results to achieve the results they desire. As Dr. Berg explains, the Oral-B® website discloses study after study conducted by or at the behest of Oral-B, and not once has an Oral-B® product ever come up short in head-to-head comparative testing against another toothbrush. The reported results of clinical studies are even more suspicious when one considers that P&G and Philips, the two primary players in the premium power toothbrush market, each claim that its toothbrush outperforms the other in clinical research settings. These results are irreconcilable and strongly suggest that clinical research is being manipulated by the big companies.

50. P&G also contends that my use of the term "magic" in describing ultrasound misleads consumers. This contention is nonsense. I use the word in a letter to consumers in our

product manual. Referring to the rubber waveguide that is nestled in the center of our product's brushhead, I state: this "is where the magic happens." I am merely pointing out from where in the brush the ultrasound emanates. No reasonable consumer would ever read my statement literally and conclude that ultrasound is "magic."

51. Indeed, P&G repeatedly uses the term "magic" in its own advertising. For instance, P&G's website advertising for its Puffs® Plus Tissues urges consumers to explore their "Magical Layer," claiming that magic is "[t]he secret behind what makes our tissues silkier than before – and more soothing for sore noses." P&G also urges consumers to "Discover all the Cleaning Possibilities" that its Mr. Clean® "Magic" Eraser has to offer. Examples of these P&G website and packaging claims are annexed hereto as Exhibit M.

52. I note that P&G engages in other types of hyperbole in its advertising. It describes its new premium Oral-B® Triumph power toothbrush as "smart" and as representing the "next generation in premium rechargeable toothbrushes." And, it describes its Hummingbird® power flosser as "amazing." Examples of P&G website advertising in this regard are attached hereto as Exhibit N.

53. Lastly, P&G argues that by emphasizing the Ultreo's® plaque removal capabilities in one minute's worth of brushing time, Ultreo will deceive consumers into believing that brushing for one minute is as effective as brushing for two minutes. This assertion is absurd. Ultreo's® website, directions for use and literature plainly disclose that we recommend a two minute brushing cycle. The brush itself has a timer reminding the user to brush for two minutes. The plain fact, however, is that many people do not brush that long. Oral-B recognizes this fact on its own website. We are simply pointing out that if a user brushes for less than one minute, they will still get a good result. Indeed, Sonicare® FlexCare has a one minute brushing cycle.

54. Ultreo's research is plainly relevant information for those who know they should brush for two minutes but who often fail to do so. No one is being misled into thinking that one minute is now the preferred length of time for brushing. Oral-B has published research on its website comparing the Oral-B® and Sonicare® in plaque removal efficacy at intervals of 15, 30, 45 and 60 *seconds*. In utilizing these parameters, is Oral-B suggesting to consumers that they should only brush for 15 seconds? No, they are trying to support a claim that its product cleans faster than a Philips product. This represents yet another example of P&G seeking to impose standards upon Ultreo when P&G itself does not live up to those standards.

55. I respectfully submit that this lawsuit is not about false advertising. As noted above, P&G engages in the very same type of advertising about which it complains in this litigation. This litigation is, instead, a calculated attempt by an aggressive market leader to stop entrepreneurial innovation in its tracks. P&G is, in short, trying to prevent new entrants, like Ultreo, from participating in this market, notwithstanding the proven safety and efficacy of a product that has generated praise from professionals and consumers alike.

Dated: November 28, 2007
Seattle, Washington



Jack Gallagher

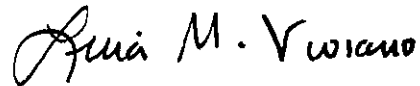
CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on November 30, 2007, I caused a copy of the foregoing **REDACTED DECLARATION OF JACK GALLAGHER** to be served upon counsel for The Procter & Gamble Company by the Court's ECF Filing System and by hand delivery to the following individual:

Laura W. Sawyer
JONES DAY
222 East 41st Street
New York, New York 10017

Attorneys for The Procter & Gamble Company

Dated: New York, New York
November 30, 2007

A handwritten signature in black ink, reading "Lina M. Viviano". The signature is written in a cursive, flowing style.

Lina M. Viviano